

AUG 2 2000

K001662

## SUMMARY OF SAFETY AND EFFECTIVENESS

### CHASE CARDIOVASCULAR PATCH

#### I. General Information

- A. Generic Name: Cardiovascular Patch
- B. Trade Name of Device: CHASE CARDIOVASCULAR PATCH
- C. Applicant's Name and Address: CHASE MEDICAL INC., Richardson, TX
- D. Pre-market Notification Number: Not assigned

#### II. Indication for Use:

The CHASE Cardiovascular Patch is indicated for cardiac and vascular patch grafting.

#### III. Device Description

The Chase Cardiovascular Patch is a knitted velour Dacron Fabric impregnated with highly purified collagen which minimizes bleeding at implant and thereby eliminates the operative preclotting step. The collagen is gradually resorbed by the patient.

#### IV. Device Classification: Class II device

#### V. Safety and Effectiveness:

Substantial Equivalence: This device is identical to the Meadox Hemashield Fabric.

#### VI. Other Safety and Effectiveness Data:

Materials: All materials are identical to materials used in similar devices that have similar intended uses.

Sterilization: Validated Gamma Radiation sterilization cycle per ISO 11137:1995 Sterilization of Health Care Products-Radiation Sterilization, Method 1 to establish Sterility Assurance Level (SAL) equal to  $10^{-6}$ .

#### Functional Testing

All functional characteristics of the Chase Cardiovascular Patch are identical to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 2 2000

CHASE Medical, Inc.  
C/O Mr. Dave Hernon  
Vice President Regulatory Affairs  
1710 Firman Drive  
Suite 100  
Richardson, TX 75081

Re: K001662  
CHASE Cardiovascular Patch  
Regulatory Class: II (two)  
Product Code: DXZ  
Dated: May 30, 2000  
Received: May 31, 2000

Dear Mr. Hernon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Dave Hernon


This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

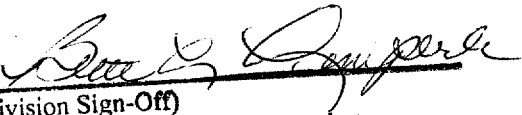


Enclosure

510(k) Number (if known): K001662

Device Name: Chase Cardiovascular Patch

Indications For Use: The Chase Cardiovascular Patch is indicated for cardiac and vascular patch grafting

  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K001662

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)